REMARKS

In response to the Office Action dated July 28, 2005, Applicants elect, *with traverse*, claims 12-13, 18-26, 32-39, 42, 45-52, 55, and 59 drawn to a composition comprising a peptide and counter-ion for prosecution on the merits (Group III). Claims 1, 2, 7-11, and 58 are cancelled herein, and new dependent method claims 60-67 correspond to these cancelled claims. Claims 60 and 61 correspond to cancelled claims 1 and 2; claims 62-64 correspond to cancelled claims 9-11; claims 65 and 66 correspond to cancelled claims 7 and 8; and claim 67 corresponds to cancelled claim 58. New claims 60 and 65 have been written to depend from claims 12 and 18, respectively. Claims 12, 17, 18, 32, and 45 have been amended to recite the term "comprising." Claims 42 and 55 have been amended to change their dependency to an elected claim. No new matter has been added by way of these amendments and new claims, such that their entry at this time is warranted.

As required, Applicants elect Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 (Teverelix) as the species of peptide. Claims 12-13, 20-29, 32-57, and 60-64 are readable thereon. Applicants also elect trifluoroacetic acid as the species of counter-ion. Claims 6, 13, 17, 32-44, 59, 61, and 67 are readable thereon.

Applicants hereby request modification of the present restriction as it contravenes the basic notions of equity based on the substantial Patent Office delay and the withdrawal of allowability of several claims in order for the restriction to be imposed. Indeed, Applicants must now essentially re-prosecute the application from the very beginning.

The Office Action states that Groups I, II, and V and Groups III and IV are related as process of making and product made. The ground for rejection is that the products as claimed can "be prepared in the absence of a counter-ion" (Office Action at p. 3). Applicants respectfully traverse, as this is incorrect. All product claims do indeed require the presence of a counter-ion. Independent claims 12, 17, and 18 clearly recite a counter-ion, and independent claims 32 and 45 clearly recite a salt that includes the counter-ion. Indeed, the process as claimed cannot be used to make other and *materially different* products that do not contain a counter-ion because the method claims all require a counter-ion as well. Also, the product as claimed cannot be made by another and *materially different* process that does not contain a counter-ion. Thus, the reasoning in making the restriction is completely flawed and Applicants respectfully request that the restriction requirement be modified as follows.

Specifically, Group I, which is drawn to a method of preparing a suspension by associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 with a counter-ion, and Group V, which is drawn to a method of preparing a lyophilized composition of a peptide corresponding to Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 and a counter-ion, should be examined together with Group III, which includes claims to suspensions of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 and a counter-ion. The subject matter of these three groups plainly overlap not only in the requirement of a counter-ion, but also in the type of peptide. It would therefore be both logical and reasonable to examine these groups together, as well as being no additional search burden, being more equitable, and complying more properly with the intent of the MPEP restriction provisions.

The Office Action argues that Groups I and V are unrelated to each other. Group I is drawn to methods of preparing a suspension comprising a peptide of the formula Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2, while Group V is drawn to a method of preparing a lyophilized composition of a peptide corresponding to Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 and a counter-ion. The additional step of lyophilizing the composition is simply freeze-drying -- a step that is not a different invention that requires restriction. Indeed, the Examiner has already acknowledged that both Group I and Group V are classified in class 514, subclass 484. Thus, there is no additional burden on the Examiner to search the same prior art for both claim groups.

For all these reasons, the restriction should be modified and Groups I, III, and V should be examined together.

The restriction should be further modified so that Groups II and IV are examined together, because both groups are related to formulations of GnRH antagonists with a counter-ion. Group II is drawn to a method of preparing a formulation by associating a GnRH antagonist with a counter-ion, while Group IV is drawn to a composition comprising a GnRH antagonist and a counter-ion. Since the subject matter of Groups II and IV are so closely related, the restriction should be modified so these groups are also examined together.

In fact, Groups I-V are all unmistakably linked together to provide a single inventive concept--a fluid, milky microcrystalline aqueous suspension. The nature of the drug and the counter-ion, each of which is present in all independent claims, do not significantly impact the basic invention. The claimed processes simply relate to salt

formation, and the claimed products are salts. A proper review of the patentability of the present product claims would effectively necessitate that all processes for preparing the product also be reviewed, such that there is no additional search burden to examine these claim groups together.

In addition, claims 27, 29, 40, 44, 53, and 57 are not directed to just any process for making products. Claims 27 and 29 are specifically directed to a process for making the product of claims 26 and 12. Claims 40 and 44 are directed to a process for making the product of claim 32, while claims 53 and 57 are directed to a process for making the product of claim 45. These claims should be examined with the elected product claims since the Examiner will already need to examine processes used to make such products in order to determine the patentability of those product claims. As such, all claim groups I-V should be examined together. In the alternative, the restriction should be modified into two claim groups -- those of present groups I, III, and V; and those of groups II and IV. In this later instance, Applicants elect the same species and the claims of new Group I (old groups I, III, and V), including claims 12-13, 18-24, and 32-67.

New claims 60 and 65 have been amended to depend from claims 12 and 18 respectively. Thus, claims 60 and 65, as well as related claims 61-64 and 66-67, are also specifically directed to a process for making the product of claims 12 and 18. Consequently, these claims should also be reviewed with the elected product claims.

Should the Examiner not agree with this position, he is invited to contact the undersigned by telephone in order to expedite the prosecution of this application.

Respectfully submitted,

Sept. 6, 2005
Date

Jeffrey A. Wolfson (Reg. No. 42,234)

WINSTON & STRAWN LLP
Customer Number: 28765

(202) 282-5770